Practitioner's Docket No. U 012951-1

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: CHUN-YING HUANG, et al

Application No.: 09/768,442

Group No.: 1614

Filed: JANUARY 24, 2001

Examiner: REBECCA COOK PHARMACEUTICAL COMPOSITION FOR THE TREATMENT OF

For: HEPATOCELLULAR CARCINOMA

Mail Stop RCE **Commissioner for Patents** P. O. Box 1450 Alexandria, VA 22313-1450 CE TO CONTRA CON

## REQUEST FOR CONTINUED EXAMINATION (RCE) (37 C.F.R. 1.114)

Applicant hereby requests continued examination, in accordance with 37 C.F.R. Section 1. 1.114, for the above identified application.

#### CERTIFICATION UNDER 37 C.F.R. SECTIONS 1.8(a) AND 1.10

(When using Express Mail, the Express Mail label number is mandatory; Express Mail certification is optional.)

I hereby certify that, on the date shown below, this correspondence is being:

#### **MAILING**

 $\bowtie$ deposited with the United States Postal Service in an envelope addressed to the Commissioner for Patents, P. O. Box 1450, Alexandria, VA 22313-1450.

### 37 C.F.R. Section 1.8(a)

37 C.F.R. Section 1.10

with sufficient postage as first class mail. 図

as "Express Mail Post Office to Addressee" Mailing Label No. EV 327550849 US (mandatory)

#### TRANSMISSION

facsimile transmitted to the Patent and Trademark Office (703)

Date: November 12, 2003

Signature

11/14/2003 SDIRETA1 00000026 09768442

01 FC:2801

385.00 OP

Geraldine Marti

(type or print name of person certifying)

• Only the date of filing (§ 1.6) will be the date used in a patent term adjustment calculation, although the date on any certificate of mailing or transmission under § 1.8 continues to be taken into account in determining timeliness. See § 1.703(f). Consider "Express Mail Post Office to Addressee" (§ 1.10) or facsimile transmission (§ 1.6(d)) for the reply to be accorded the earliest possible filing date for patent term adjustment calculations.

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### NOTE: 37 C.F.R. § 1.114 Request for continued examination:

"(a) If prosecution in an application is closed, an applicant may request continued examination of the application by filing a submission and the fee set forth in  $\S 1.17(e)$  prior to the earliest of:

- (1 Payment of the issue fee, unless a petition under § 1.313 is granted;
- (2) Abandonment of the application; or
- (3) The filing of a notice of appeal to the U.S. Court of Appeals for the Federal Circuit under 35 U.S.C. 141, or the commencement of a civil action under 35 U.S.C. 145 or 146, unless the appeal or civil action is terminated.
- (b) Prosecution in an application is closed as used in this section mans that the application is under appeal, or that the last Office action is a final action ( $\S$  1.113), a notice of allowance ( $\S$  1.311), or an action that otherwise closes prosecution in the application.
- (c) A submission as used in this section includes, but is not limited to, an information disclosure statement, an amendment to the written description, claims, or drawings, new arguments, or new evidence in support of patentability. If reply to an Office action under 35 U.S.C. 132 is outstanding, the submission must meet the reply requirements of § 1.111.
- (d) If an applicant timely files a submission and fee set forth in § 1.17(e), the Office will withdraw the finality of any Office action and the submission will br entered and considered. If an applicant files a request for continued examination under this section after appeal, but prior to a decision on the appeal, it will be treated as a request to withdraw the appeal and to reopen prosecution f the application before the examiner. An appeal brief under § 1.192 or a reply brief under § 1.193(b), or related papers, will not be considered a submission under this section."
- NOTE: An applicant may file a submission under 37 C.F.R. 1.114 containing only an information disclosure statement (37 C.F.R. 1.97 and 1.98) in an application subject to a notice of allowance under 35 U.S.C. § 151. An appeal brief or a reply brief (or related papers) will not be considered a submission under 37 C.F.R. 1.114. See 37 C.F.R. 1.114(d). The submission, however, may consist of the arguments in a previously filed appeal brief or reply brief, or may simply consist of a statement that incorporates by reference the arguments in a previously filed appeal brief or reply brief. In addition, a previously filed amendment after final may satisfy this submission requirement. American inventor's Protection act of 1999, Question & Answer A5.
- NOTE: Even though an RCE is improper (e.g., because it was filed before the prosecution is closed), an amendment submitted with the RCE will still be entered and considered by the examiner since it was timely filed and responsive to the non-final Office action in compliance with 37 C.F.R. 1.111. American Inventor's Protection Act of 1999, Question & Answer A4.
- **WARNING**:

35 U.S.C. 132(b) and Section 1.114 provide for the continued examination of an application and not examination of a continuing application). Accordingly, the Office will not permit an applicant to obtain continued examination on the basis of claims that are independent and distinct from the claims previously claimed and examined. Notice of March 10, 2000, 65 Fed Reg 14865, at 14868.

**WARNING**:

The provisions of 37 C.F.R. 1.114 also do not apply (1) to a provisional application; (2) an application for a utility or plant patent filed under 35 U.S.C. 111(a) before June 8, 1995; (3)) an international application filed under 35 U.S.C. 363 before June 8, 1995 (4) a patent under reexamination or (5) an application for a design patent. 37 C.F.R. § 1.114(e).

WARNING:

The PTO has pointed out why § 1.97(b) does not provide that an information disclosure statement will be considered it is filed within three months after the date of a request for continued examination under § 1.114. The PTO explained that since an RCE filing is a reply under 35 U.S.C. 132, the applicant may be entitled to patent term adjustment if the Office does not act on an application containing a request for continued examination under § 1.114 within four months. See 35 U.S.C. 154(b)(1)(A)(ii). Thus, the Office cannot delay action on RCE applications for three months to determine whether an information disclosure statement will be filed. The Office, however, is adopting provisions (§ 1.103(c)) for a limited suspension of action after the filing of a request for continued examination under § 1.114, for the applicant to obtain additional time (prior to the issuance of the next Office action) to provide an information disclosure statement (or amendments, or an affidavit or declaration) after the filing of the RCE. See Notice of August 16, 2000, "Request for Continued Examination Practice and Changes to Provisional Application Practice; Final Rule", 65 Fed. Reg., pages 50091-50105, at page 50100 (comment 11); OG: September 5, 2000, pages 13-24.

WARNING: One of the time periods excluded from patent term adjustment is the time consumed by a continued examination request under 35 U.S.C. 132(b) (§ 1.114(b)(1)).

WARNING: The Office will not suspend action in an application when a reply by the applicant is outstanding. 35 U.S.C. 133 requires an applicant to "prosecute the application" within six months of an Office action (or a shorter period as set in the Office action) to avoid abandonment of the application. If an applicant files a request for continued examination but does not also provide any submission (in reply to the prior Office action) within the period for reply to the prior Office action, the application is abandoned by operation of law (35 U.S.C. 133).

The Office will treat a request for continued examination under  $\S$  1.114 containing a bona fide submission that is not fully responsive to the prior Office action under the practice set forth in  $\S$  1.135(c). In addition, under the limited suspension of action provisions of  $\S$  1.103(c), an applicant must still file a request for continued examination practice in compliance with  $\S$  1.114, but may obtain additional time (prior to the issuance of the next Office action) to provide an information disclosure statement, amendments, or an affidavit or declaration after the filing of the request for continued examination.

See Notice of August 16, 2000. "Request for Continued Examination Practice and Changes to Provisional Application Practice; Final Rule", 65 Fed. Reg., pages 50091-50105, at page 50102 (comment 20); OG: September 5, 29000, ages 13-24, Page 50102.

WARNING: Section 197(b) does not provide that an information disclosure statement will be considered if it is filed within three months after the date of request for continued examination under § 1.114.

NOTE: There is no limit to the number of times the fee for continued examination may be submitted. Notice of March 10, 2000, 65 Fed. Reg. 14865. at 14868.

NOTE: Unlike a continuation application, a continued examination request can utilize the mailing procedure of 37 C.F.R. 1.8. See 37 C.F.R. Section 1.8(a)(2)(i)(A).

### TIME REQUEST IS BEING MADE

2. 7	This requ	est is beir	submitted (check appropriate item(s) below):				
-	i.	[X]	Prior to abandonment of the application				
	ii.	[X]	Payment of the issue fee [X] Prior to payment of issue fee [] Issue fee has been paid but a petition under Section 1.313 has been granted				
	iii.	[X]	Prior to a decision on appeal to the Board of Patent Appeals & Interferences  [ ] A notice is being separately sent to the Board of Patent Appeals & Interferences that this Request for Continued Examination is being filed.				
NOTI		If such a notice is not sent to the Board, they may refuse to vacate a decision rendered after the filing of the RCE but before recognition by the Office of the RCE request under Section 1.114.					
	iv.	[X]	Appeal to the U.S. Court of Appeals of the Federal Circuit under 35 U.S.C. 145 or Commencement of a civil action under 35 U.S.C. 146 [X] Prior to the filing of such appeal or commencement of civil action Such appeal or commencement of civil action has been terminated				

## **ENCLOSURES**

	<u>not</u> auto sion is/a	omatically enter any prior unentered amendment(s). Hereware:	vith as the required	
	[X] Request hereby to enter unetered amendment(s) of MAY 21, 2003.			
	[X]	An amendment		
	[]	New arguments	to to Co	
	[]	New evidence in support of patentability	Chronical	
	[X]	RULE 132 DECLARATION	THE TOUS WE	
WARNI	NG:	utstanding, the submission must		
	[]	Other:		
		FEE FOR REQUEST (37 C.F.R. Section 1.1	7(e)).	
4. Thi	is applica	ation is on behalf of:		
	[X]	Small entity (and status is still as small entity)	\$ 385.00	
	[]	Other than a small entity	\$ 770.00	
		Continued Prosecution Request Fee	\$ <u>385.00</u>	
		FEE FOR CLAIMS		
NOTE:	"The fee (cf. 1.53	for continued examination under Section 1.114 (Section 1.17(e)) does (d)(3)(ii))." See Notice of March 10, 2000, 65 Fed Reg 14865, at 148	not include additional claims fee 68.	
	37 C.F.R	R. $1.53(d)(3)$ : "The filing fee for a continued prosecution application for	îled under this paragraph is:	
		(i) The basic filing fee as set forth in Section 1.16; and		
		(ii) Any additional Section 1.16 fee due based on the number of clai. after entry of any amendment accompanying the request for an appli entry of any amendments under Section 1.116 unentered in the prior requested to be entered in the continued prosecution application."	cation under this paragraph and	

5. The fee for claims (37 C.F.R. Section 1.16(b)-(d)) has been calculated as shown below:

[ ] Firs	t Presentation of Mult	iple Dependen	t Claim	+ \$145 =	\$	·	+ \$290 =	\$
Indep.	Minus		=	x \$43 =	\$		x \$86 =	\$
Total	Minus		=	x \$9 =	\$		x \$18 =	\$
	Claims Remaining After Amendment	Highest No. Previously Paid For	Present Extra	Rate	Addit. Fee	OR	Rate	Addit. Fee
	(Col.1)	(Col. 2)	(Col. 3)	SMALL	ENTITY		MALL ENTI	

<sup>\*</sup> If the entry in Col. 1 is less than the entry in Col. 2, write "0" in Col. 3,

**WARNING**:

See 37 C.F.R. Section 1.116.

# **EXTENSION OF TIME**

(If an extension of time is appropriate complete (a) or (b), as applicable)

- 6. The proceedings herein are for a patent application, and the provisions of 37 C.F.R. Section 1.136(a) apply.
  - (a) [X] Applicant petitions for an extension of time, the fees for which are set out in 37 C.F.R. Section 1.17(a)(1)-(4), for the total number of months checked below:

Extension for (months)	Fee for other than small entity	Fee for small entity	
[ ] one month [ ] two months [ ] three months [X] four months	\$ 110.00 \$ 420.00 \$ 950.00 \$1,480.00	\$ 55.00 \$ 210.00 \$ 475.00 \$ 740.00	

Fee \$\_740.00\_

If an additional extension of time is required, please consider this a petition therefor.

(check and complete the next item, if applicable)

<sup>\*\*</sup> If the "Highest No. Previously Paid For" IN THIS SPACE is less than 20, enter "20".

<sup>\*\*\*</sup> If the "Highest No. Previously Paid For" IN THIS SPACE is less than 3, enter "3".

The "Highest No. Previously Paid For" (Total or Indep.) is the highest number found in the appropriate box in Col. 1 of a prior amendment or the number of claims originally filed.

		[]		_ months has already been sec _ is deducted from the total fe requested.		
	•		Extension	on fee due with this request	\$	
				OR		
	(b)	[]	conditional petition and a	o extension of time is required. authorization to pay the necessal ant has inadvertently overlook sion of time.	ary fees to	provide fo
			TOTAL	FEE(S) DUE		
WARNI	ING:	The fee	e for continued examination under	Section 1.114 may not be deferred. 3	37 C.F.R. Se	ection 1.53(f).
7. Th	e total f	fee(s) du	ne is/are:			
	Conti	nued Pro	osecution Fee (Section 1.17)	(e))	\$	385.00
	Fee(s)	for add	litional claims (if any) (Sect	ion 1.16(b)-(d))	\$	· <del></del>
	Extens	sion of t	time fee (if any) (Section 1.1	17(a)(1)-(4))	\$	740.00
				Total Fee(s) Due:	\$	1,125.00
			PAYMENT	OF FEE(S) DUE		
8. Ple	ease pay	the fee	(s) for this continued exami	nation application as follows:		
	[X]	Check	k is attached for the sum of		\$	1,125.00
	[]	Charg	ge Account the sum	of	\$	
Section	n 1.17(a	a)(1)-(4)	to	(s) for Section 1.17(e), Section	1.16(b)-(	d) and/or
	[x]	Depos	sit Account <u>12-0425</u>			

## **INVENTORSHIP**

NOTE: Any change of inventors must be via the procedure set forth in 37 C.F.R. Section 1.48. See Notice of March 10, 2000, 65 Fed Reg 14865, at 14868.

9.	This applic	cation as amended names as inventors:				
	[]	the same inventors as previously designated for the claims.				
	[]	fewer than the inventors previously designated and a statement accompanies this request for the deletion of the name or names of the person or persons who are not inventors of the invention now being claimed.				
	[]	a person not named previously as an inventor a 1.48 is/has separately: [ ] being filed [ ] been filed	and a petition under 37 C.F.R. Section			
		DEFERRAL OF EXAMINA	ATION			
10.	[]	A request for deferral of examination accompaexamination.	nnies this request for continued			
			IGNATURE OF PRACTITIONER			
Reg.	. No.: 33,7		ANET I. CORD (type or print name of practitioner)			
Tel. No.: (212)708-1935			ADAS & PARRY P.O. Address			
Customer No.: 00140			26 WEST 61 <sup>ST</sup> STREET			